UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 09-10179-GAO

UNITED STATES OF AMERICA, ex rel. CHRISTOPHER DRENNEN, Relator.

v.

FRESENIUS MEDICAL CARE HOLDINGS, INC., d/b/a FRESENIUS MEDICAL CARE NORTH AMERICA, Defendant.

OPINION AND ORDER March 6, 2012

O'TOOLE, D.J.

Relator, Christopher Drennen (identified in the original complaint as "John Doe"), filed this action under the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. §3730. His First Amended Complaint alleges that Fresenius, the nation's largest dialysis treatment provider, performed certain hepatitis B and ferritin tests on dialysis patients at a rate exceeding the frequency authorized for reimbursement by Medicare's National Coverage Determination ("NCD") manual. He alleges that Fresenius billed the costs of these tests to Medicare without supporting documentation showing that the increased frequency of testing was medically necessary. As a consequence, he alleges, Fresenius fraudulently obtained reimbursements it was not entitled to.

According to the allegations of the First Amended Complaint, which are taken as true for present purposes, Drennen was employed by Fresenius in Mobile, Alabama, as an area manager from January 2006 until January 2008. As an area manager, he managed ten Fresenius dialysis clinics and reviewed, investigated, and complied with all audits performed on those facilities. He

claims that, through his role as area manager, he obtained independent knowledge that Fresenius performed hepatitis B and ferritin tests and billed those tests to Medicare, despite the fact that it was not, under applicable rules, entitled to reimbursement for those tests. Specifically, Drennen alleges that he first learned of the excess tests as a result of a May 2006 audit of three of the facilities under his management. He found that these facilities were performing hepatitis tests and billing those tests to Medicare, despite the fact that proper justification for the testing (and the billing) was lacking. Drennen then reviewed the testing records for all ten facilities under his management. He discovered that between May 1, 2005 and May 31, 2006, a total of 2,574 hepatitis B tests were administered and billed to Medicare. Drennen alleges that these tests were performed more frequently than NCD requirements, were not medically necessary, and did not have the required medical documentation or physician orders. Drennen alleges that this fraudulent billing amounted to \$40,338 improperly billed to Medicare. He makes similar, though somewhat less detailed, allegations about excess testing and billing for ferritin. Based on this information, Drennen alleges a nationwide scheme to bill Medicare for medically unnecessary testing over a ten year period.

Fresenius had moved to dismiss the First Amended Complaint on the grounds that it does not allege fraud with the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure and that Drennen is not an original source of this information and thus is subject to the FCA's "public disclosure bar" to suit.

<u>I.</u> Rule 9(b)

The heightened pleading requirements of Rule 9(b) apply to claims brought under the FCA. <u>U.S. ex rel. Karvelas v. Melrose-Wakefield Hosp.</u>, 360 F.3d 220, 227 (1st Cir. 2004). To meet the burden of Rule 9(b), a plaintiff must plead the false claims with particularity,

specifically the "time, place and content" of the false claims. <u>Doyle v. Hasbro, Inc.</u>, 103 F.3d 186, 194 (1st Cir. 1996). Such details may include the specific claims submitted, who filed the claims, the content of the claims, the timing of the submissions, and the amount of payment sought from the government. <u>U.S. ex rel. Westmoreland v. Amgen, Inc.</u>, 738 F. Supp. 2d 267, 275 (D. Mass 2010) (citing <u>Karvelas</u>, 360 F.3d at 233). <u>See also U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.</u>, 579 F.3d 13, 30 (1st Cir. 2009) (complaint survived a motion to dismiss on 9(b) grounds where the plaintiff identified the medical providers, the illegal kickbacks, the time periods and locations, and the actual filing of the false claims themselves). This is not a strict checklist. The important point is that some specific information for some claims must be pleaded in order to satisfy Rule 9(b). <u>Id.</u> (citing <u>U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.</u>, 290 F.3d 1301, 1312 n.2 (11th Cir. 2002)).

The defendant argues that Drennen has not met the Rule 9(b) pleading standard because he has not pled the names of the Fresenius employees who submitted the false claims, the doctors, whose orders were violated by frequent testing, or when the employees submitted false bills to Medicare for the tests. That specific information is not necessarily required. Drennen has identified the initials of six patients on whom the sixty-four unnecessary tests were performed, the type of hepatitis B test performed, the one-year period when these tests were performed, the locations of the three clinics that performed the tests, and the cost billed for each test. He has also alleged that Fresenius submitted claims to Medicare for payment of all sixty-four tests. He further alleges that, by reason of Fresenius' national billing practices, this billing likely occurred at Fresenius' other facilities throughout the country. Drennen has pleaded the specific false claims with enough particularity to satisfy the requirements of Rule 9(b).

II. Public Disclosure Bar

The FCA includes erected a jurisdictional bar which forecloses a qui tam action where the relator "attempts to free-ride by merely repastinating previously disclosed badges of fraud." U.S. ex rel. Ondis v. City of Woonsocket, 587 F.3d 49, 53 (1st Cir. 2009). This public disclosure bar was specifically designed to discourage opportunistic behavior and prevent "parasitic" suits. Id. (quoting U.S. ex rel. McKenzie v. BellSouth Telecomms., Inc., 123 F.3d 935, 943 (6th Cir. 1997)). The qui tam action is barred if (1) there has been a public disclosure of the allegations in the complaint, (2) the public disclosure occurred in a manner listed in the FCA statute, and (3) the FCA suit is based upon the publicly disclosed allegations. U.S. ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 728 (1st Cir. 2007), abrogated on other grounds by Allison Engine Co. v. U.S. ex rel. Sanders, 553 U.S. 662 (2008). However, even if all three criteria are met, the suit may survive where relator is an "original source" pursuant to 31 U.S.C. § 3730(e)(4)(B).

Here, there is little dispute that the elements of the public disclosure bar are met. In support of denying jurisdiction, Fresenius argues that Drennen is not an "original source" as established by the FCA and that, therefore, the case must be dismissed for lack of subject matter jurisdiction.

The FCA defines an original source as "an individual . . . who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions and who has voluntarily provided the information to the Government." 31 U.S.C. § 3730(e)(4)(B). Thus, in order to qualify as an original source, the relator must have direct and independent knowledge

Rockwell Int'l Corp. v. United States, 549 U.S. 457, 470-71 (2007). Knowledge is direct if it is acquired through the relator's own efforts and not through an intervening party. <u>U.S. ex rel.</u> O'Keeffe v. Sverdup Corp., 131 F. Supp. 2d 87, 93 (D. Mass. 2001). This direct knowledge must be the product of the plaintiff's own labor. <u>Id.</u> Knowledge is independent if it is not dependent on the public disclosure. <u>Ondis</u>, 587 F.3d at 59. Thus, in order for the claim to succeed, the relator has the burden to show that he has direct and independent knowledge of the information underlying the claim for fraud. Rockwell, 549 U.S. at 476.

Here, the First Amended Complaint details Drennen's position at Fresenius, the business practices he observed during his employment, his supervision of ten dialysis clinics, and the research he performed of the clinics' testing records. The Complaint also describes the nationwide computer and billing system used by Fresenius to submit claims to Medicare. Drennen used this computer system to research Fesenius' billing practices before 2006 for both hepatitis B and ferratin testing. The specific data provided by Drennen, the patients' initials, the billing prices for each type of test, and the testing frequency all sufficiently establish his direct and independent knowledge.

Fresenius claims that Drennen cannot be an original source unless he has direct and independent knowledge of "every Fresenius facility nationwide with respect to every Hepatitis B and Ferritin test given to every patient from 2001 to the present" and direct and independent knowledge of the medical history of every patient at every clinic and the billing practices of every facility. (Def's Mem. in Supp. of Mot. to Dismiss 4-5 (dkt. no. 46).) This is simply not the

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case. Denner describes Fresenius' nationwide computer system, as well as its standardized use of

a common system for billing Medicare. He alleges personal familiarity with the system and how

it has been used to bill for the relevant tests. That is sufficient. For the foregoing reasons, the

defendant's Motion (dkt. no. 45) to Dismiss Relator's First Amended Complaint is DENIED.

It is SO ORDERED.

/s/ George A. O'Toole, Jr.

United States District Judge

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